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Practitioner's Docket No. U 014681-4

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____

Inventor(s)

for _____

Title of invention

OR

In re application of: **Prasad K. DESHPANDE, et al**

Serial No.: 10/749,932

Group No.: 1614

Filed: December 31, 2003

Examiner: N/A

For: **BENZOQUINOLIZINE-2-CARBOXYLIC ACID ARGININE SALT TETRAHYDRATE**

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. 1.97(b))**

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

*(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)*

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37 C.F.R. 1.8(a)

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- ☒ with sufficient postage as first class mail.

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- ☐ transmitted by facsimile to the Patent and Trademark Office, to **(703) 872-9306**

Date: December 17, 2004

Signature

Janet L. Cord

(type or print name of person certifying)

- * Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: 37 C.F.R. 1.98(b):

- (1) *Each U.S. patent listed in an information disclosure statement must be identified by inventor, patent number, and issue date.*
- (2) *Each U.S. patent application published listed in an information disclosure statement shall be identified by applicant, patent application publication number, and publication date.*
- (3) *Each U.S. application listed in an information disclosure statement must be identified by the inventor, application number, and filing date.*
- (4) *Each foreign patent or published foreign patent application listed in an information disclosure statement must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application.*
- (5) *Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.*

WARNING: *No extension of time can be had under 37 C.F.R. § 1.36 (a) or (b) for filing an IDS. 37 C.F.R. § 1.97(f).*

NOTE: *The "filing date of a national application" under 37 C.F.R. 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 C.F.R. 1.97(b)(2).*

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. 1.97(b).

NOTE: *"No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."*

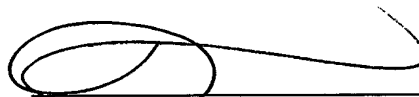
NOTE: *"An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

NOTE: *"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

If a fee is required, please charge deposit account 12-0425.



SIGNATURE OF PRACTITIONER

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Janet I. Cord

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Prasad K. **DESHPANDE**, et al.

Serial No.: 10/749,932

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Attorney Docket No.: U 014681-4

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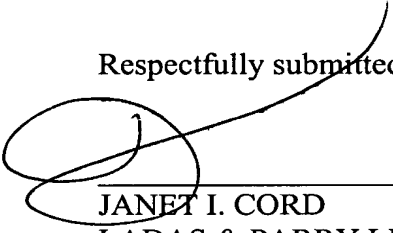
P. O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

We draw the attention of the Examiner to the attached references which are also listed on the attached Form PTO-1449.

Respectfully submitted,



JANET I. CORD
LADAS & PARRY LLP
26 WEST 61ST STREET
NEW YORK, NEW YORK 10023
REG. NO. 33,778 (212) 708-1935

CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10*

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Date: December 9, 2004



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FORM PTO-1449

U. S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

SERIAL NO.

U 014681-4

10/749,932

APPLICANT

Prasad K. Deshpande, et al.

FILING DATE

GROUP

12/31/2003

1614

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | FILING DATE IF APPROPRIATE |
|---------------------|----|--------------------|---------|-----------------|-------------------------------|
| | AA | 4,563,459 | 01/1986 | Groher et al. | |
| | AB | 3,845,770 | 11/1974 | Theeuwes et al. | |
| | AC | 3,916,899 | 11/1975 | Theeuwes et al. | |
| | AD | 3,536,809 | 10/1970 | Applezweig | |
| | AE | 3,598,123 | 08/1971 | Zaffaroni | |
| | AF | 4,008,719 | 02/1977 | Theeuwes et al. | |
| | AG | 6,514,986 | 02/2003 | de Souza et al. | |
| | AH | 6,136,806 | 10/2000 | Hittel | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION | |
|--|----|--------------------|---------|---------|-------------|----|
| | | | | | YES | NO |
| | AJ | 9414794 | 07/1994 | WO | | X |
| | AK | 6-145167 | 05/1994 | JP | | X |
| | AL | 9415938 | 07/1994 | WO | | |
| | AM | 98/58923 | 12/1998 | WO | | X |

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | | |
|--|----|---|
| | AO | Asahina, Y. et al. "Recent advances in structure activity relationships in new quinolones", <i>Prog. Drug Res.</i> (1992), 38: 57-106 |
| | AP | Japanese patent application 6-145167, dated May 24, 1994 |
| | AQ | Cooper, C.S. et al. "Preparation and in Vitro and in Vivo Evaluation of Quinolones with Selective Activity against Gram Positive Organisms", <i>J. Med. Chem.</i> 1392-1398 |
| | AR | English abstract of WO 98/58923, dated December 30, 1998 |
| | AS | English abstract of WO 94/14794, dated July 7, 1994 |
| | AT | Chemical Abstracts 136:147733 |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U 104681-4

10/749,932

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OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | |
|----|--------------------------------|
| AA | Chemical Abstracts 134:141378 |
| AB | Chemical Abstracts 134:141377 |
| AC | Chemical Abstracts 135: 300896 |
| AD | Chemical Abstracts 130: 322834 |
| AE | Chemical Abstracts 129:339430 |
| AF | Chemical Abstracts 129:310840 |
| AG | Chemical Abstracts 129:245024 |
| AH | Chemical Abstracts 129: 239390 |
| AI | Chemical Abstracts 127: 358825 |
| AJ | Chemical Abstracts 123: 164953 |
| AK | Chemical Abstracts 124: 86783 |
| AL | Chemical Abstracts 124: 170377 |
| AM | Chemical Abstracts 124:343084 |
| AN | Chemical Abstracts 127: 302924 |
| AO | Chemical Abstracts 131: 153420 |
| AP | Chemical Abstracts: 136:2738 |

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| FORM PTO-1449 U. S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) | ATTY. DOCKET NO. | SERIAL NO. |
| | U 104681-4 | 10/749,932 |
| | APPLICANT | |
| | Prasad K. Deshpande, et al. | |
| | FILING DATE | GROUP |
| | 12/31/2003 | 1614 |

| REFERENCE DESIGNATION | | | U.S. PATENT DOCUMENTS | | |
|-----------------------|----|--------------------|-----------------------|------------------|-------------------------------|
| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | FILING DATE IF APPROPRIATE |
| | AA | 6,329,391 | 12/2001 | Ledoussal et al. | |
| | AB | 4,382,892 | 05/1983 | Hayakawa et al. | |
| | AC | 5,859,026 | 01/1999 | Ito et al. | |
| | AD | 5,889,009 | 05/1999 | Miyake et al. | |
| | AE | 6,121,285 | 09/2000 | Takemura et al. | |
| | AF | 6,184,388 | 02/2001 | Takemura et al. | |
| | AG | 3,984,403 | 10/1976 | Fujisawa et al. | |

| FOREIGN PATENT DOCUMENTS | | | | | |
|--------------------------|----|--------------------|---------|---------|-------------|
| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION |
| | | | | | YES NO |
| | AH | 0394553 | 06/1995 | EP | X |
| | AI | 0572259 | 12/1993 | EP | |
| | AJ | 0287951 | 10/1988 | EP | |

| OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.) | | |
|--|----|--|
| | AK | European Patent Specification 0394553 B1, dated June 21, 1995 |
| | AL | Alsina J. et al. "Active Carbonate Resins for Solid-Phase Synthesis Through the Anchoring of a Hydroxyl Function. Synthesis of Cyclic and Alcohol Peptides", <i>Tetrahedron Letters</i> , (1997), 38(5): 883-886 |
| | AM | Edwards W.B. et al. "Generally Applicable, Convenient Solid-Phase Synthesis and Receptor Affinities of Octreotide Analogs", <i>J. Med. Chem.</i> , (1994), 37(22): 3749-3757 |
| | AN | Dhople, A.M. and M.A. Tbanez. " <i>In vivo</i> susceptibility of mycobacterium leprae to ofloxacin either singly or in combination with Rifampicin and Rifabutin", <i>Arzneimittel-Forschung</i> , (1994), 44(4): 563-565 |
| | AO | Haustein U.F. et al. "Topical quinolone nadifloxacin (OPC-7251) in bacterial skin disease: clinical evaluation in a multicenter open trial and in vitro antimicrobiological susceptibility testing", <i>J. Dermatological Treatment</i> , (1997), 8: 87-92 |
| | AP | Hashimoto, Koji et al. "A Practical Synthesis of (S)-(-)-Nadifloxacin: Novel Acid-Catalyzed Racemization of Tetrahydroquinaldine Derivative", <i>Chem. Pharm. Bull.</i> , (1996), 44(4): 642-645 |
| | AQ | Irish, D. et al. "Control of an outbreak of an epidemic methicillin-resistant <i>Staphylococcus aureus</i> also resistant to mupirocin", <i>J. Hospital Infection</i> , (1996), 39: 19-26 |

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|----------|-----------------|
| EXAMINER | DATE CONSIDERED |
|----------|-----------------|

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

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10/749,932

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Prasad K. Deshpande, et al.

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U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | FILING DATE IF APPROPRIATE |
|---------------------|----|--------------------|---------|-----------------|-------------------------------|
| | AA | 4,642,355 | 02/1987 | Nakamura et al. | |
| | AB | 4,051,247 | 09/1977 | Schuppan et al. | |
| | AC | 3,924,042 | 12/1975 | Gerster et al. | |
| | AD | 3,985,882 | 10/1976 | Gerster et al. | |
| | AE | 4,399,134 | 08/1983 | Ishikawa et al. | |
| | AF | 4,404,207 | 09/1983 | Stern et al. | |
| | AG | 4,416,884 | 11/1983 | Ishikawa et al. | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION | |
|--|----|--------------------|---------|---------|-------------|----|
| | | | | | YES | NO |
| | AH | 0304087 | 02/1989 | EP | | |
| | AI | 0241206 | 10/1987 | EP | | |
| | AJ | 9914214 | 03/1999 | WO | | |

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | | |
|--|----|--|
| | AK | Kido, M. et al. "Crystal Structures of Nadifloxacin Anhydride and its Hemihydrate", <i>Chem. Pharm. Bull.</i> , (1994), 42(4):872-876 |
| | AL | Takahashi et al. "Reduction of in vitro Clastogenicity Induced by the Mixture of Optical Isomers of Nadifloxacin during Storage", <i>Arzneim.-Forsch./Drug Res.</i> , (1995), 45(1): 195-197 |
| | AM | Sloan et al. "Definition and attainment of high purity of organic compounds", Chapter 2, 179-182, <i>Physics and Chemistry of the Organic Solid State</i> , eds. D. Fox, Labes and Weissberer. Interscience Publishers, London. 1963 |
| | AN | Morita, S. et al. "An efficient synthesis of a key determinate towards (S)-(-)-Nadifloxacin", <i>Tetrahedron: Asymmetry</i> , (1995), 6(1): 245-254 |
| | AO | Morita, S. et al. "Synthesis and Antibacterial Activity of the Metabolites of 9-Fluoro-6,7-dihydro-8-(4-hydroxy-1-piperidyl)-5-methyl-1-oxo-1 <i>H</i> ,5 <i>H</i> -benzo[<i>i,j</i>]quinolizine-2-carboxylic acid (OPC-7251)", <i>Chem. Pharm. Bull.</i> , (1990), 38(7): 2027-2029 |
| | AP | Ishikawa, H. et al. "Studies on Antibacterial agents. I. Synthesis of Substituted 6,7-Dihydro-1-oxo-1 <i>H</i> ,5 <i>H</i> -benzo[<i>i,j</i>]quinolizine-2-carboxylic acids", <i>Chem. Pharm. Bull.</i> , (1989), 37(8): 2103-2108 |
| | AQ | English translation of Yamada, Hirao et al. "Evaluation of the <i>in vitro</i> drug efficacy of Nadifloxacin Cream", <i>Iyakuin Kenkyu</i> , (2000), 31(8): 519-524 |

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|---------------------|----|--------------------|---------|-----------------|-------------------------------|
| | AA | 4,443,447 | 04/1984 | Gerster et al. | |
| | AB | 4,472,406 | 09/1984 | Gerster et al. | |
| | AC | 4,472,407 | 09/1984 | Stern et al. | |
| | AD | 4,535,161 | 08/1985 | Hayakawa et al. | |
| | AE | 4,552,879 | 11/1985 | Ishikawa et al. | |
| | AF | 4,594,347 | 06/1986 | Ishikawa et al. | |
| | AG | 4,599,418 | 07/1986 | Irikura et al. | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION | |
|--|----|--------------------|---------|---------|-------------|----|
| | | | | | YES | NO |
| | AH | 02131483 | 05/1990 | JP | | |
| | AI | 02188589 | 07/1990 | JP | | |
| | AJ | 0018404 | 04/2000 | WO | | |

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | | |
|--|----|--|
| | AK | English abstract of Japanese patent 02131483, dated May 21, 1990 |
| | AL | English abstract of Japanese patent 02188589, dated July 24, 1990 |
| | AM | English translation of Yamada, Hiroaki, et al. "Bioequivalency of 1% Nadifloxacin lotion and 1% of Nadifloxacin cream", <i>Iyaku hin Kenkyu</i> , (2000), 31(8): 525-528 |
| | AN | Berge, Stephen M. et al. "Pharmaceutical Salts", <i>J. Pharmaceutical Sciences</i> , (1977), 66(1): 1-19 |
| | AO | Abstract of Koike, M. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(5): 998-1021 |
| | AP | Abstract of Koike, M. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(5): 1022-1033 |
| | AQ | Abstract of Fujita, S. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(6): 1156-1176 |

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| | AA | 5,185,337 | 02/1993 | Fujii et al. | |
| | AB | 6,034,100 | 03/2000 | Adachi et al. | |
| | AC | 4,935,420 | 06/1990 | Ueda et al. | |
| | AD | 5,639,886 | 06/1997 | Zerbes et al. | |
| | AE | 5,869,661 | 02/1999 | Ochi et al. | |
| | AF | 4,638,067 | 01/1987 | Culbertson et al. | |
| | AG | 4,665,079 | 05/1987 | Culbertson et al. | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION | |
|--|----|--------------------|---------|---------|-------------|----|
| | | | | | YES | NO |
| | AH | 0185095 | 11/2001 | WO | | |
| | AI | 0908181 | 04/1999 | EP | | |
| | AJ | 9420105 | 09/1994 | WO | | |

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | | |
|--|----|---|
| | AK | Abstract of Koike, M. et al. <i>Yakubutsu Dotai</i> , (1990), 5(2): 199-208 |
| | AL | Abstract of Yasuo, A. et al. <i>Yakuri to Chiryō</i> , (1990), 18(4): 1717-1730 |
| | AM | Abstract of Hayakawa, R. et al. <i>Hifu</i> , (1990), 32(2): 217-230 |
| | AN | Abstract of Asada, Y. et al. <i>Yakuri to Chiryō</i> , (1990), 18(4): 1717-1730 |
| | AO | Abstract of Awogi, T. et al. <i>Iyaku hin Kenkyū</i> , (1990), 21(4): 626-635 |
| | AP | Abstract of Matsuzawa, A. et al. <i>Iyaku hin Kenkyū</i> , (1990), 21(4): 636-646 |
| | AQ | Abstract of Nagao, T. et al. <i>Iyaku hin Kenkyū</i> , (1990), 21(4): 647-662 |

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|---------------------|----|--------------------|---------|-------------------|-------------------------------|
| | AA | 4,822,801 | 04/1989 | Domagala et al. | |
| | AB | 5,097,032 | 03/1992 | Domagala et al. | |
| | AC | 5,051,509 | 09/1991 | Nagano et al. | |
| | AD | 5,607,942 | 03/1997 | Petersen et al. | |
| | AE | 5,677,316 | 10/1997 | Ao et al. | |
| | AF | 4,777,175 | 10/1988 | Culbertson et al. | |
| | AG | 4,874,764 | 10/1989 | Ueda et al. | |

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| | | | | | YES | NO |
| | AH | 9744034 | 11/1997 | WO | | X |
| | AI | 05339238 | 12/1993 | JP | | |
| | AJ | 58090511 | 05/1983 | JP | | |

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| | | |
|--|----|--|
| | AK | English abstract of WO 97/44034, dated November 27, 1997 |
| | AL | English abstract of JP 5339238, dated December 21, 1993 |
| | AM | English abstract of JP 58090511, dated May 30, 1983 |
| | AN | Abstract of Matsuzawa, A. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(4): 663-670 |
| | AO | Abstract of Hashimoto, K. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(4): 671-677 |
| | AP | Abstract of Furukawa, M. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(5): 989-997 |
| | AQ | Abstract of Yoshimura, S. et al. <i>Iyakuhin Kenkyu</i> , (1990), 21(5): 1034-1052 |

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| | AA | 4,563,459 | 01/1986 | Groher et al. | |
| | AB | 3,845,770 | 11/1974 | Theeuwes et al. | |
| | AC | 3,916,899 | 11/1975 | Theeuwes et al. | |
| | AD | 3,536,809 | 10/1970 | Applezweig | |
| | AE | 3,598,123 | 08/1971 | Zaffaroni | |
| | AF | 4,008,719 | 02/1977 | Theeuwes et al. | |
| | AG | 5,436,367 | 07/1995 | Iwata et al. | |

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| | | | | | YES | NO |
| | AH | 63192753 | 08/1988 | JP | | |
| | AI | 57081486 | 05/1982 | JP | | |
| | AJ | 57176987 | 10/1982 | JP | | |

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| | | |
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| | AK | English abstract of JP 63192753, dated August 10, 1988 |
| | AL | English abstract of JP 57081486, dated May 21, 1982 |
| | AM | English abstract of JP 57176987, dated October 30, 1982 |
| | AN | Abstract of Nakagiri, N. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(6): 1144-1155 |
| | AO | Abstract of Aoki, M. et al. <i>Iyaku hin Kenkyu</i> , (1990), 21(6): 1177-1202 |
| | AP | Abstract of Matsuzawa, A. et al. <i>Iyaku hin Kenkyu</i> , (1991), 22(1): 61-76 |
| | AQ | Abstract of Kurokawa, I. et al. <i>J. Am. Acad. Dermatol.</i> , (1991), 25(4): 674-681 |

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| | AA | 5,348,961 | 09/1994 | Iwata et al. | |
| | AB | 4,997,943 | 03/1991 | Iwata et al. | |
| | AC | 5,290,934 | 03/1994 | Ueda et al. | |
| | AD | 5,420,140 | 05/1995 | Perrin | |
| | AE | 4,935,420 | 06/1990 | Ueda et al. | |
| | AF | 4,880,806 | 11/1989 | Ueda et al. | |
| | AG | 4,894,458 | 01/1990 | Masuzawa et al. | |

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| | | DOCUMENT NUMBER | DATE | COUNTRY | TRANSLATION |
| | | | | | YES NO |
| | AH | 02188570 | 07/1990 | JP | |
| | AI | 0068229 | 11/2000 | WO | |
| | AJ | 0185728 | 11/2001 | WO | |

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| | AK | English abstract of JP 02188570, dated July 24, 1990 |
| | AL | Abstract of Bojar, R.A. et al. <i>Journal of Investigative Dermatology</i> , (1994), 103(3): 405 |
| | AM | Abstract of Smith, C.M. <i>Journal of Investigative Dermatology</i> , (1997), 108(3): 123 |
| | AN | Abstract of Hayakawa, R. et al. <i>Hifu</i> , (1998), 40(2): 165-171 |
| | AO | Abstract of Fujio, N. et al. <i>Yakuri to Chiryo</i> , (1998), 26(7): 1119-1132 |
| | AP | Kido, M. et al. "The Absolute Configuration of (R)-(+)-Nadifloxacin", <i>Chem. Pharm. Bull.</i> , (1996), 44(2): 421-423 |
| | AQ | Miller, M.A. et al. "Development of Mupirocin Resistance Among Methicillin-Resistant <i>Staphylococcus aureus</i> After Widespread Use of Nasal Mupirocin Ointment", <i>Infection Control and Hospital Epidemiology</i> , (1996), 17(12): 811-813 |

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| | AA | 6,514,986 | 2/2003 | Shivkumar, et al. | |
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| | | | | | YES | NO |
| | AH | 9926940 | 06/1999 | WO | | X |
| | AI | 0919553 | 06/1999 | EP | | |
| | AJ | 0230295 | 07/1987 | EP | | |

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| | AK | English abstract of WO99/26940, dated June 3, 1999 |
| | AL | Mateu-de-Antonio, E.M. and M. Martín. "In vitro efficacy of several antimicrobial combinations against <i>Brucella canis</i> and <i>Brucella mlitensis</i> strains isolated from dogs", <i>Veterinary Microbiology</i> , (1995), 45: 1-10 |
| | AM | Nishijima, S. et al. "Sensitivity of <i>Staphylococcus aureus</i> , Isolated from Skin Infections in 1994, to 19 Antimicrobial Agents", <i>J. International Medical Research</i> , (1995), 23: 328-334 |
| | AN | Nishijima, S. et al. "Activity of Eight Fluoroquinolones against Both Methicillin-Susceptible and -Resistant <i>Staphylococcus aureus</i> Isolated from Skin Infections", <i>J. Dermatology</i> , (1995), 22: 153-155 |
| | AO | Nishijima, S. et al. "Activity of Nadifloxacin Against Methicillin-Resistant <i>Staphylococcus aureus</i> Isolated from Skin Infections: Comparative Study with Seven Other Fluoroquinolones", <i>J. International Medical Research</i> , (1996), 24: 12-16 |
| | AP | Nishijima, S. et al. "Sensitivity of <i>Staphylococcus aureus</i> and <i>Streptococcus pyogenes</i> Isolated from Skin Infections in 1992 to Antimicrobial Agents", <i>J. Dermatology</i> , (1994), 21: 233-238 |
| | AQ | Abstract of Kurokawa, I. et al. <i>European Journal of Dermatology</i> , (1999), 9(1): 25-28 |

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| | | | | | YES | NO |
| | AH | 0209758 | 02/2002 | WO | | |
| | AI | 0541086 | 05/1993 | EP | | |
| | AJ | 0342675 | 11/1989 | EP | | |

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| | AK | Abstract of Komagata, Y. et al. <i>Japanese Journal of Antibiotics</i> , (1998), 51(2): 130-136 |
| | AL | Abstract of Gollnick, H. et al. <i>Dermatology</i> , (1998), 196(1): 119-125 |
| | AM | Abstract of Nishijima, S. et al. <i>J. International Medical Research</i> , (1997), 25(4): 210-213 |
| | AN | Abstract of Akamatsu, H. et al. <i>J. International Medical Research</i> , (1995), 23(1): 19-26 |
| | AO | Abstract of Takahashi, N. et al. <i>Arzneimittel-Forschung</i> , (1995), 45(2): 195-197 |
| | AP | Abstract of Takahashi, N. et al. <i>Arzneimittel-Forschung</i> , (1994), 44(11): 1265-1268 |
| | AQ | Abstract of Patel, M.V. et al. 39 th ICAAC at San Diego, (Sept. 26-29, 1999), Poster No. F0558 |

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| | | | | | YES | NO |
| | AH | 9731000 | 08/1997 | WO | | |
| | AI | 0300735 | 01/1989 | EP | | |
| | AJ | 9724128 | 07/1997 | WO | | |

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | | |
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| | AK | Chemical Abstract: Doc. No. 123-334723. Vogt, K. et al. <i>Drugs</i> (1995), 49 (Supp.2): 266-268 |
| | AL | Chemical Abstract: Doc. No. 123:334716. Nishijima, S. et al. <i>Drugs</i> (1995), 49 (Supp.2): 230-232 |
| | AM | Chemical Abstract: Doc. No. 124: 21098. Bojar, R.A. et al. <i>Drugs</i> (1995), 49 (Supp.2): 164-167 |
| | AN | Chemical Abstract: Doc. No. 122:213914. Morita, S. et al. <i>Tetrahedron: Asymmetry</i> (1995), 6(1): 245-254 |
| | AO | Chemical Abstract: Doc. No. 119: 4810. Vogt, K. et al. <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> (1992), 11(10): 943-945 |
| | AP | Chemical Abstract: Doc. No. 113:231188. Morita, S. et al. <i>Chem. Pharm. Bull.</i> (1990), 38(7): 2027-2029 |
| | AQ | Chemical Abstract: Doc. No. 112: 229223. Muto, N. et al. <i>J. Immunoassay</i> (1990), 11(1): 1-16 |

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| | | | | | YES | NO |
| | AH | 9414794 | 07/1994 | WO | | X |
| | AI | 6-145167 | 05/1994 | JP | | |
| | AJ | 9415938 | 07/1994 | WO | | |

OTHER ART (Including Author, Title, Date, Pertinent Dates, Etc.)

| | | |
|--|----|---|
| | AK | English abstract of WO 94/14794, dated July 7, 1994 |
| | AL | Japanese patent 6-145167, dated May 24, 1994 |
| | AM | Chemical Abstract: Doc. No. 112: 191305. Koike, M. et al. <i>J. Chromatogr.</i> (1990), 526(1): 235-239 |
| | AN | Chemical Abstract: Doc. No. 112: 178631. Ishikawa, H. et al. <i>Chem. Pharm. Bull.</i> (1989), 37(8): 2103-2108 |
| | AO | Chemical Abstract: Doc. No. 112:52083. Kawabata, S. et al. <i>Chemotherapy</i> (1989), 37(9): 1160-1178 |
| | AP | Abstract of Iwahara, K. et al. <i>European Journal of Dermatology</i> , (1999), 9(4): 276-277 |
| | AQ | Abstract of Radl, S. <i>Archiv der Pharmazie</i> , (1996), 329(3): 115-119 |

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| | | | | | YES | NO |
| | AH | 9858923 | 12/1998 | WO | | X |
| | AI | 03/099815 | 12/2003 | WO | X | |
| | AJ | 02/09758 | 2/2002 | WO | X | |

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| | AK | Abstract of Andriole, V.T. <i>Drugs</i> , (1993), 46 (Supp.3): 1-7 |
| | AL | Ball, Peter. "The Quinolones: History and Overview", Chapter 2, pages 1-28. <u>The Quinolones</u> , Second Edition. Academic Press, 1998 |
| | AM | English abstract of WO 98/58923, dated December 30, 1998 |
| | AN | Domagala, John M. "Structure-activity and structure-side-effect relationships for the quinolone antibacterials", <i>J. Antimicrobial Chemotherapy</i> (1994), 33: 685-706 |
| | AO | Suto, M.J. et al. "Fluoroquinolones: Relationships between Structural Variations, Mammalian Cell Cytotoxicity and Antimicrobial Activity", <i>J. Med. Chem.</i> , (1992), 35: 4745-4750 |
| | AP | Abstract of Yamakawa, T. et al. <i>J. Antimicrobial Chemotherapy</i> , (2002), 49(3): 455-465 |
| | AQ | Hooper, David C. "Mechanisms of fluoroquinolone resistance", <i>Drug Resistance Update</i> , (1999), 2: 38-55 |

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| | AH | 01/85095 | 11/2001 | WO | X | |
| | AI | 00/68229 | 11/2000 | WO | X | |
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| | AK | Ince, Dilek and David C. Hooper. "Mechanisms and Frequency of Resistance to Gatifloxacin in Comparison to AM-1121 and Ciprofloxacin in <i>Staphylococcus aureus</i> ", <i>Antimicrobial Agents and Chemotherapy</i> , (2001), 45(10): 2755-2764 |
| | AL | Fournier, B. and David C. Hooper. "Mutations in Topoisomerase IV and DNA Gyrase of <i>Staphylococcus aureus</i> : Novel Pleiotropic Effects on Quinolone and Coumarin Activity", <i>Antimicrobial Agents and Chemotherapy</i> , (1998), 42(1): 121-128 |
| | AM | Zhao, Xilin et al. "Killing of <i>Staphylococcus aureus</i> by C-8-Methoxy Fluoroquinolones", <i>Antimicrobial Agents and Chemotherapy</i> , (1998), 42(4): 956-958 |
| | AN | Breines, David M. et al. "Quinolone Resistance Locus <i>nfxD</i> of <i>Escherichia coli</i> Is a Mutant Allele of the <i>parE</i> Gene Encoding a Subunit of Topoisomerase IV", <i>Antimicrobial Agents and Chemotherapy</i> , (1997), 41(1): 175-179 |
| | AO | Fournier, B. and David C. Hooper. "Expression of the Multidrug Resistance Transporter NorA from <i>Staphylococcus aureus</i> Is Modified by a Two-Component Regulatory System", <i>J. Bacteriology</i> , (2000), 182(3): 664-671 |
| | AP | Mandell, Lionel A. et al. "Antimicrobial Safety and Tolerability: Differences and Dilemmas", <i>CID</i> , (2001), 32 (Suppl.1): S72-S79 |
| | AQ | Gootz, Thomas D. and Katherine E. Brighty. "Chemistry and Mechanism of Action of the Quinolone Antibacterials", Chapter 2, pages 29-80. <u>The Quinolones</u> , Second Ed. Academic Press, 1998 |

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| | AK | Takenouchi, T. et al. "Hydrophilicity of Quinolones Is Not an Exclusive Factor for Decreased Activity in Efflux-Mediated Resistant Mutants of <i>Staphylococcus aureus</i> ", <i>Antimicrobial Agents and Chemotherapy</i> , (1996), 40(8): 1835-1842 |
| | AL | Zhao, Xilin et al. "DNA topoisomerase targets of the fluoroquinolones: A strategy for avoiding bacterial resistance", <i>Proc. Natl. Acad. Sci. USA</i> , (1997), 94: 13991-13996 |
| | AM | Takei, M. et al. "Target Preference of 15 Quinolones against <i>Staphylococcus aureus</i> , Based on Antibacterial Activities and Target Inhibition", <i>Antimicrobial Agents and Chemotherapy</i> , (2001), 45(12): 3544-3547 |
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Prasad K. Deshpande, et al.

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U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | FILING DATE IF APPROPRIATE |
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FOREIGN PATENT DOCUMENTS

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